THE HONORABLE BARBARA J. ROTHSTEIN

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WESTERN DISTRICT OF WASHINGTON
BY DEPUTY

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WESTERN DISTRICT OF WASHINGTON
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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE PHENYLPROPANOLAMINE (PPA) PRODUCTS LIABILITY LITIGATION This document relates to all actions	MDL Docket No 1407 CASE MANAGEMENT ORDER NO 1

I. INTRODUCTION

On November 16, 2001, an initial conference was held in order to address issues dealing with the structure and purposes of the leadership of plaintiffs and defendants in this multi-district litigation During the course of that conference, various issues relating to discovery, experts, use of technology, class actions, and federal-state coordination were also discussed.

At the conclusion of the conference, the Court directed the parties to submit an agreed upon Case Management Order No. 1, to the extent possible, addressing a fact discovery schedule, deposition and document production procedures, expert disclosure

164

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and discovery, and any other matters felt necessary to promote the efficient and timely progress of this litigation.

By order dated November 21, 2001, this Court appointed Lead and Liaison Counsel for plaintiffs and defendants The Court had previously indicated that Lead Counsel for each side, because of their knowledge of the skills, experience and compatibility of counsel involved in this litigation, should propose for Court approval the names of counsel to serve on various Committees Those proposals have been made and the Court has acted thereon. The Court also requested the submission no later than December 14, 2001, of a Joint Proposed Case Management Order No. 1, to address the issues discussed during the initial conference, and any other topics

The parties have now submitted a proposed Case Management Order No 1, together with opposing submittals regarding various aspects of CMO No 1 about which the parties disagree After review and consideration of the parties' submissions, the Court hereby orders as follows:

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II. STAY OF PROCEEDINGS IN CASES TRANSFERRED TO MDL 1407

All proceedings in any case transferred to MDL 1407, now or in the future, are stayed except as to the specific proceedings outlined in this Order, any pending motions to remand presently before this Court, or in any subsequent order of the Court. All prior written discovery to which responses have not yet been served is deemed withdrawn All dates on which responsive pleadings are due are hereby stayed until further notice, and all scheduling orders are hereby vacated. Nothing herein shall extend or modify the time permitted for removal of any case to federal court, nor shall any portion of this Order be deemed to apply to any case or matter now or hereafter pending in any state court unless that state court so orders.

III. STATUS CONFERENCES, MOTIONS, PLEADINGS AND SERVICE

A. Status Conferences. *Status Conferences shall be regularly scheduled* by the Court to permit substantial advance notice to all parties. Except as otherwise provided herein, and to accommodate the schedules of the Court and parties, oral argument or hearings on any motion will be scheduled to coincide with calendared Status Conferences. Counsel may attend and participate in Status Conferences, oral arguments and hearings by telephone at the Court's discretion by prior arrangement with the Court's chambers Any hearing or oral argument deemed necessary by the Court on motions that require a ruling on an expedited basis will be scheduled to permit notice of at least two (2) business days. If circumstances warrant, the Court may shorten the notice period

B. Motions. Motion practice shall be governed by applicable Federal and Local Rules except as otherwise provided herein or in any subsequent Case

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Management Order. Absent an Order of the Court, briefs in response to all motions shall be filed twenty-one (21) days after the date of service. Reply memoranda shall be filed within seven (7) days after service of the response. Oral argument or hearing on a motion will be scheduled to coincide with the first regularly scheduled Status Conference occurring after seven (7) days from the scheduled date, as extended by the Court, for the filing of Reply memoranda.

C. **Notice to Parties by the Court.** Notice by the Court to Plaintiffs' Liaison Counsel and Defendants' Liaison Counsel of any matter, ruling, order, schedule or court hearing relating to all actions, shall be considered by the Court to be Notice to all parties in MDL 1407. Notice by the Court of any matter, ruling, order, schedule of court hearing relating only to individual actions shall be given to counsel of record for that action, Plaintiffs' Liaison Counsel and Defendants' Liaison Counsel.

D. **Service of Pleadings, Motions and Other Documents.** Lead Counsel and any party filing with the Court a pleading, motion, or other document relating to all actions shall provide one (1) copy to Plaintiffs' Liaison Counsel, one (1) copy to Defendants' Liaison Counsel, and one (1) copy to opposing Lead Counsel by overnight mail or hand delivery. In addition, an electronic version of any document filed shall be provided at the time of service to the respective Liaison Counsel by electronic mail, on a floppy disk, or on CD-ROM in either WordPerfect or Microsoft Word format. If any document filed is comprised of or contains a paper copy of an electronic image of said document, the electronic image of said document(s) shall be similarly served. Service on Plaintiffs' and Defendants' Liaison Counsel constitutes service on all plaintiffs' counsel and all defendants' counsel, respectively. Service and distribution by Liaison

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Counsel to other attorneys of record may be made via U S. Mail and either e-mail, overnight courier service or facsimile transmission, reserving to any counsel of record the right to waive, in writing, all or any aspect of said service.

E. Communication with the Court. All communications with the Court should be through Lead or Liaison Counsel. Correspondence from individual plaintiff or defense counsel directly to the Court is strongly discouraged except when requested or the circumstances require direct contact. In any event, a copy of any such correspondence must be simultaneously served on Liaison Counsel.

IV. STATEMENT OF ISSUES

No later than 5 days prior to the next status conference, Lead Counsel for Plaintiffs and Defendants shall submit separate reports to the Court identifying and describing the legal and factual issues they believe will need to be addressed in these MDL proceedings. The reports by Lead Counsel shall not exceed 24 pages in length.

V. FACT DISCOVERY OF DEFENDANTS

Discovery as to defendants shall be governed by applicable Federal Rules of Civil Procedure and Local Rules except as otherwise provided herein or in any subsequent Case Management Order. Fact discovery has begun against certain, but not all defendants, in various state court proceedings This Court has taken into consideration the present status and progress of discovery against various groups of defendants in fashioning a discovery schedule that will aid in fostering state and federal court coordination of PPA cases, and completing the tasks undertaken in this MDL 1407 with reasonable dispatch in keeping with the needs and expectations of litigants.

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A. Completion of Fact Discovery. Fact discovery of all defendants, as divided into three distinct groups, shall be completed as follows:

(1) Group I Defendants. Group I Defendants are American Home Products Corporation, Novartis Consumer Health Inc., Bayer Corporation, SmithKline Beecham, Perrigo, and Chattem, and any related entities. Fact discovery as to Group I Defendants shall be completed on or before December 31, 2002.

(2) Group II Defendants. Group II Defendants are those defendants presently named in any case now docketed in this MDL 1407 not designated as Group I Defendants, such as Schering-Plough and Thompson/Delaco. Fact discovery as to Group II Defendants shall be completed on or before February 28, 2003.

(3) Group III Defendants. Group III Defendants are those defendants who are named in any action transferred to this MDL 1407 after the date of this Order Fact discovery as to each such defendant shall be completed on or before 15 months following the first day of the month following the docketing of the first action naming said defendant in this MDL 1407.

B. Discovery Disputes All disputes regarding the scope or conduct of fact discovery shall be resolved pursuant to the standards and procedures set forth in the Federal Rules of Civil Procedure as augmented by the Local Rules of this District, except as otherwise provided herein.

C. *Confidentiality of Produced Materials or Deposition Testimony*. The Court has entered *Case Management Order No 2 (Confidentiality of Material Produced and Testimony Relating Thereto)* pursuant to the joint submittal of same by the parties.

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D. Preservation of Documents

The Court will enter *Case Management Order No. 3 (Preservation of Documents)* following the submittal of the positions of the parties regarding the content thereof

E. Production of Documents

(1) Master Request For Production of Documents. Document production by most Group I Defendants is and has been ongoing in several state and federal court cases, all in response to virtually identical requests for production propounded by many of the plaintiffs' counsel named as members of the Plaintiffs' Steering Committee or Discovery Committee Attached at Tab A is the *Master Requests For Production of Documents Addressed To All Defendants* ("Master Requests For Production") which incorporates the requests previously made and responded to by Group I Defendants and is hereby deemed served on all defendants named in any action transferred to this MDL 1407. In the absence of an agreement or further order of the Court, no further document requests may be propounded to the Defendants without leave of Court.

(2) Prior Production and Responses to Requests to Produce. To the extent that any Group I Defendant has produced documents in response to requests for production also contained in the Master Requests for Production, that production is hereby deemed to be production to the same requests contained in the Master Requests for Production Similarly, to the extent that any Group I Defendant has responded to requests to produce also contained in the Master Requests for Production, those responses are hereby deemed to have been made to the same requests contained in the Master Requests for Production. All objections to production

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requests raised in a response made by any Group I Defendant are preserved to the extent existing as of the date hereof, and all rights held by plaintiff(s) to contest any objections made are similarly preserved and intact.

(3) Document Production Deadlines.

(a) Group I Defendants Each Group I Defendant shall produce all documents maintained in hard copy responsive to the Master Requests for Production on or before February 28, 2002, except for those documents withheld pursuant to an assertion of privilege, work product or objection. Group I Defendants shall produce all documents maintained in electronic format responsive to the Master Requests for Production on or before March 30, 2002, except for those documents withheld pursuant to an assertion of privilege, work product or objection. The parties shall meet and confer as soon as practicable to resolve disputes concerning withheld documents. Motions to compel should only be filed on those issues that cannot in good faith be resolved. The Court expects that document production will be completed by the deadlines above, and that no further extensions will be necessary

(b) Group II Defendants. Each Group II Defendant shall respond to the Master Request for Documents no later than February 28, 2002 and produce all documents maintained in hard copy responsive to the Master Requests for Production no later than March 30, 2002, except for those documents withheld pursuant to an assertion of privilege, work product or objection . Group II Defendants shall produce all documents maintained in electronic format responsive to the Master Requests for Production on or before March 30, 2002, except for those documents withheld pursuant to an assertion of privilege, work product or objection. The parties

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shall meet and confer as soon as practicable to resolve disputes concerning withheld documents. Motions to compel should only be filed on those issues that cannot in good faith be resolved. The Court expects that document production will be completed by the deadlines above, and that no further extensions will be necessary.

(c) Group III Defendants. Each Group III Defendant shall respond to the Master Request for Documents within sixty (60) days of the transfer to this MDL 1407 of the first action in which it is named and produce all documents responsive to the Master Requests For Production on a rolling basis within one hundred twenty (120) days thereafter, except for those documents withheld under an assertion of privilege or protection, or where an objection has been asserted The parties shall meet and confer as soon as practicable to resolve disputes concerning withheld documents Motions to compel should only be filed on those issues that cannot in good faith be resolved.

(4) Manner of Production. With respect to all responsive documents or materials kept or maintained in either tangible form or in any electronic form, all defendants shall produce those documents or materials in "hard" copy, with appropriate identifying Bates numbering or labeling which shall include an alpha prefix identifying the defendant producing same. However, this provision shall not prohibit or otherwise impact any subsequent motion by plaintiffs to seek the production from any defendant of all responsive documents or materials kept or maintained in electronic form in the same format as they are kept or maintained. All defendants shall, to the extent reasonably possible, produce on a "rolling" basis, such that documents or materials should be made available for production and produced at regular intervals rather than accumulated with

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all other documents for production at the end of the document production period permitted herein. Each copy of a document shall convey the exact information and appearance of the original document unless redacted pursuant to a stated objection or privilege, in which event the fact that a redaction has been made shall be made apparent on the face of the document produced. If color is material to appreciating or comprehending the content of a document, parties shall honor reasonable requests for either the production of an original document for inspection and copying or production of a color image of the document. Similarly, the parties shall comply with all reasonable requests for inspection and copying of an original document for all copies deemed unreadable or illegible, in whole or in part. The reasonable reproduction costs incurred by defendants of providing "hard" copies shall be borne by plaintiffs pursuant to applicable Federal and Local Rules.

(5) **Document Images and Objective Databases**. If a defendant chooses or has chosen to create electronic images of documents or materials produced in "hard" copy, duplicates of said images shall be produced to plaintiffs on CD-ROM disks on or before that defendant's document production deadline. The electronic images produced shall be in the same electronic format as utilized by defendant in creating and maintaining the electronic images Provided, however, that should a defendant choose to create electronic images of only a select group of documents, such that the selection reflects the work product of its attorneys in conjunction with this litigation, then production shall not be required The reasonable reproduction costs incurred by defendants of providing copies of CD-ROM disks containing images of

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documents produced shall be borne by plaintiffs pursuant to applicable Federal and Local Rules.

Any defendant that has created an objective database of documents produced in response to production requests of plaintiffs shall produce that database to plaintiffs. Provided, however, that should a defendant choose to create an objective database of only a select group of documents produced, such that the selection reflects the work product of its attorneys in conjunction with this litigation, then production of that database shall not be required. Defendants are permitted to redact database fields that contain subjective work product material. If a defendant seeks to withhold the database because it cannot redact the subjective materials, the defendant must first show good cause to the Court why it cannot segregate objective and subjective data. The same procedure will apply to plaintiffs' databases if sought by defendants during discovery. Plaintiffs will not be assessed costs for producing databases that defendants have prepared. However, if a defendant must incur additional costs to remove subjective material from the database, plaintiffs will bear the responsibility for those additional costs.

(6) **Document Depositories** Lead Counsel for each side may establish a document depository for purposes it deems appropriate and necessary to accomplish their obligations to their respective constituencies in this MDL 1407. Each side shall administer and bear the costs of its own depository.

(7) **Authentication of Documents**. Pursuant to the stipulation of the parties, it is hereby ordered that the copies of all documents maintained in "hard" form produced by any defendant are deemed to be a true and accurate copy of documents in

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the possession and control of that defendant, except as otherwise indicated on the face of the copy produced. It is further ordered that the "hard" copies of all documents maintained in electronic form produced by any defendant are deemed to be a true and accurate representations of the data or other information maintained in electronic format by that defendant, except as otherwise indicated on the face of the "hard" copy produced.

(8) *Assertion of Privilege in Response to Production Requests*. Any party that withholds the production of requested documents or materials, regardless of the manner in which they are kept or maintained, on the ground of any privilege or application of the work-product doctrine must specify in writing, as to each document or thing not produced, the specific privilege(s) or doctrine(s) it is relying upon to withhold each document ("Privilege Log") Each Privilege Log shall describe each document or thing to which a privilege or work product doctrine is asserted in sufficient detail to reasonably permit the party seeking discovery to assess whether or not to dispute any such assertion of privilege or application of the work product doctrine Each party so withholding shall provide the Court and opposing Liaison Counsel a copy of the party's Privilege Log on or before thirty (30) days after the deadline for the production of "hard" copies of responsive documents or materials kept or maintained in tangible form and, with respect to responsive documents kept or maintained in electronic format, within thirty (30) days after the production deadline for "hard" copies of those documents or materials

F. Interrogatories. A First Set of Interrogatories has been propounded to and answered by many Group I Defendants in several state and federal court cases

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The interrogatories served have been virtually identical, and counsel serving same are included among the plaintiffs' counsel hereby named as members of the Plaintiffs' Steering Committee or Discovery Committee. Attached at Tab B is the *Master First Set of Interrogatories Addressed To All Defendants* ("Master First Set of Interrogatories") which incorporates the interrogatories previously propounded and answered by many Group I Defendants, and is hereby deemed served on all defendants named in any action transferred to this MDL 1407

(1) Prior Answers to Interrogatories To the extent that any Group I Defendant has answered interrogatories also contained in the Master First Set of Interrogatories, those answers are hereby deemed to be responses to the same interrogatories contained in the Master First Set of Interrogatories. All objections to such interrogatories raised in a response made by any Group I Defendant are preserved to the extent existing as of the date hereof, and all rights held by plaintiff(s) to contest any objections made are similarly preserved and intact.

(2) Interrogatory Answer Deadlines for Defendants.

(a) Group I Defendants Each Group I Defendant shall respond to all interrogatories contained in the Master First Set of Interrogatories no later than January 15, 2002. The parties shall meet and confer as soon as practicable to resolve disputes concerning objections thereto. Motions to compel should only be filed on those issues that cannot in good faith be resolved.

(b) Group II Defendants. Each Group II Defendant shall respond to all interrogatories contained in the Master First Set of Interrogatories no later than February 28, 2002 The parties shall meet and confer as soon as practicable to

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resolve disputes concerning objections thereto. Motions to compel should only be filed on those issues that cannot in good faith be resolved.

(c) Group III Defendants. Each Group III Defendant shall respond to all interrogatories contained in the Master First Set of Interrogatories within sixty (60) days of the transfer to this MDL 1407 of the first action in which it is named. The parties shall meet and confer as soon as practicable to resolve disputes concerning withheld documents Motions to compel should only be filed on those issues that cannot in good faith be resolved.

G. Fact Depositions All fact depositions shall be conducted pursuant to applicable Federal Rules of Civil Procedure and Local Rules, and as further specified below.

(1) Deposition Notices In addition to the information required by applicable Rule, each deposition notice shall include the name, if known, of the primary examiner(s) designated by the party noticing the deposition, and the date, time and place of the deposition. In order for counsel to make arrangements for adequate deposition space, whenever feasible, counsel who intend to attend a deposition noticed in MDL 1407 should provide notice to the individual counsel signing the Notice of Deposition Deposition notices shall state whether the deposition is to be videotaped and, if so, the name, firm and address of the videotape recorders.

(2) Cross-Notices Between State Court Cases and These Proceedings. In order to avoid duplicative discovery and to prevent the unnecessary expenditure of judicial resources and the resources of the parties, steps should be taken to encourage counsel in related state court proceedings to coordinate their depositions

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with MDL 1407 depositions. Plaintiffs' Liaison Counsel shall copy all known plaintiffs' state liaison counsel (by mail, courier, facsimile or electronic mail) on all deposition notices filed by plaintiffs in MDL 1407 and invite state court counsel to cross-notice the deposition. Defendants' Liaison Counsel shall provide Plaintiffs' Liaison Counsel and plaintiffs' known state liaison counsel with at least thirty (30) days notice of any cross-notice in these proceedings by defendants of a deposition originally noticed in a state court. Any motion to quash or stay any such cross-notice must be filed more than ten (10) days prior to the scheduled date of the cross-noticed deposition The filing of any such motion will not delay the cross-noticed deposition, unless otherwise ordered by the Court. Absent grant of any such motion to quash or stay, no party shall re-notice the deposition of any witness already deposed under the terms of this Order unless permitted by the Court for good cause shown. If a deposition was originally noticed in this proceeding, whether or not later cross-noticed in state court proceedings, MDL counsel shall conduct the initial phase of the deposition. If a deposition was originally noticed in a state court proceeding and is later cross-noticed in this MDL proceedings, the state court counsel shall conduct the initial phase of the deposition. In either instance, questioning by state court counsel will not be counted against the time permitted for questioning pursuant to this MDL proceeding as described below. Regardless of which counsel conducts the initial examination of the deponent, subsequent questioning shall not be redundant or repetitive, although clarification of prior testimony may be sought if reasonably calculated to elicit testimony that adds to the substance of prior testimony. Nothing in this provision shall be construed as an

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injunctive or equitable order affecting state court proceedings. Rather, this provision is intended to reflect this Court's desire for voluntary state-federal coordination.

(3) Number of Depositions, Former Employees. The defendants shall make available all present employees requested by plaintiffs for deposition, subject to the defendants' right to object to the taking of any particular employee's deposition for good cause shown Plaintiffs shall in good faith take only those depositions deemed reasonably necessary under the circumstances of this case. Each defendant shall take reasonable steps to make available requested former employees, to the extent possible If a defendant is unable, despite its best good faith efforts, to produce former employees, then the defendant shall provide upon request the former employee's last known address and shall cooperate in any effort to obtain this Court's, or another court's assistance to compel the former employee's attendance at the deposition. Plaintiffs shall not contact former employees without permission of the former employer defendant As to each named defendant, plaintiffs shall be limited to a total of twenty (20) depositions of identified individuals, including former employees. In addition, plaintiffs may notice up to five (5) depositions pursuant to Fed. R. Civ P. 30(b)(6) as to each defendant regardless of the number of deponents produced by said defendant in response to each such deposition noticed, provided that the particular matters identified in a notice on which examination is requested do not duplicate any matters identified in connection with a prior Rule 30(b)(6) deposition of that defendant, notice of which was properly served on plaintiffs pursuant to the terms of this Order. Absent agreement by the defendant, plaintiffs may apply to the Court to conduct further

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depositions only upon a showing of good cause and the specific identification of the individual(s) sought to be deposed

(4) Scheduling. Plaintiffs may begin depositions of fact witnesses on January 20, 2002. If a deposition occurs before document production is completed, and documents received after the deposition raise additional questions for the witness, plaintiffs may renew the deposition upon a showing of good cause. To the extent practicable, counsel shall consult with opposing counsel and, if ethically permitted, potential deponents in an effort to schedule depositions at mutually convenient times and locations. Counsel for deponents who are employees of defendants are expected to cooperate, to the extent reasonably possible, in the scheduling of depositions requested by plaintiffs. The Court will resolve any deposition scheduling issues that Lead Counsel or their designees are unable to resolve.

(5) Length of Direct Examination in Fact Depositions. The examination by the party noticing the deposition of a present or former employee of a defendant shall be no more than seven (7) hours of actual examination time absent agreement or further order of this Court upon a showing of good cause. The Court expects that if a deposition requires additional time the parties will make a good faith effort to agree on an extension before coming to the Court for resolution. Direct examinations that are reasonably believed to require more than seven hours to complete shall be scheduled, to the extent possible consistent with the witness's schedule, for sufficient consecutive days for completion

(6) Postponements. Once a deposition has been scheduled, it shall not be taken off calendar, postponed, rescheduled, or relocated less than five (5)

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calendar days in advance of the date it is scheduled to occur, except upon agreement of counsel or by leave of Court for good cause shown. Given the large number of attorneys involved in this litigation, the unavailability of counsel shall not be grounds for postponing a deposition if another attorney from the same firm who is familiar with the case or one who represents a party with similar interests is available to attend. If a motion is made to permit the rescheduling of a deposition on the grounds of unavailability of counsel, the moving party shall certify to the Court that neither an attorney from the same firm who is familiar with the case nor one who represents a party with similar interests is able to attend the scheduled deposition.

(7) **Attendance**. Unless otherwise agreed to by the parties, depositions may be attended only by one representative of each party (other than counsel for the party), the deponent, the deponent's attorney (if not counsel for a defendant), attorneys of record in MDL 1407 or state PPA related cases, court reporters, videographers, and any person who is assisting in the litigation and whose presence is reasonably required by counsel conducting or defending the deposition. Upon application, and for good cause shown, the court may permit attendance by a person who does not fall within any of the categories set forth in the previous sentence Attendees at any deposition shall execute an acknowledgment that they are bound by the provisions of Case Management Order No. 2. If during the course of any deposition, the examination involves information or documents which any defendant claims to be confidential pursuant to Case Management Order No. 2 entered in this litigation, attendees at the deposition are limited to those permitted access to information designated confidential pursuant to that Order. Those portions of

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depositions deemed confidential pursuant to said Order will be treated and handled pursuant to the requirements of that Order. Unnecessary attendance by counsel at depositions is discouraged and may not be compensated in any fee application to the Court.

(8) Production of Documents Witnesses subpoenaed or noticed to testify and to produce documents shall be noticed and served with the subpoena or deposition notice and document request at least thirty (30) days before the scheduled deposition. Depending upon the quantity of documents to be produced, some time may be needed for inspection of the documents before the interrogation commences Responsive documents that are identical to those already produced to the Plaintiffs' do not have to be produced by the deponent, but the deponent bears the burden of demonstrating, if necessary, prior production

(9) Potential Deposition Exhibits. Parties will disclose to the deponent's counsel at least ten (10) days before a deposition the documents they expect to use during examination. As with issues regarding the length of depositions, the Court expects that if a party fails to disclose documents, the parties will make a good faith effort to agree how to proceed with the deposition before coming to the Court for resolution.

(10) Location of Depositions. Unless otherwise agreed to, any deposition of

(a) plaintiff shall take place within the federal district in which that plaintiff resides;

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(b) current and former employees and officers will take place in the federal district of such employees' or officers' place of business. Defense counsel will make reasonable efforts to obtain the agreement of former employees of defendants to appear at the same location as current employees of the same defendant. Absent such agreement, that deposition will take place either within the federal district in which the former employee resides or at a location mutually agreeable to the former employee and the parties.

H. Conduct of Depositions.

(1) Cooperation. Counsel are expected to cooperate with, and be courteous to, each other and deponents during the course of any deposition. Counsel shall refrain from engaging in colloquy during depositions. There shall be no smoking or use of other tobacco products or eating in any room in which a deposition is being conducted, including before, during or after a deposition, or in the deposition room during deposition recesses. Beverages will be permitted. Counsel shall recess from time to time during the deposition for meals and to permit periods of rest or refreshment reasonably required by the deponent, stenographer(s) and/or counsel conducting or defending the deposition.

(2) Deposition Day. Absent agreement of the parties to the deposition, a deposition day shall be no longer than seven (7) hours of actual examination time.

(3) *Continuance of Deposition* *If a deposition is not completed by* 1:00 p m. on a Friday, the deposition will recommence on the next business day, subject to the availability of the witness. If the witness is not available for deposition on the next business day, the deposition will continue on a date to be agreed upon by

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counsel or, if agreement cannot be reached, a date specified in a notice of continued deposition. Where a notice of continued deposition is required, service of notice ten (10) or more days prior to the date specified for the continued deposition shall be deemed adequate notice.

(4) Examination. The party noticing a fact deposition shall designate no more than two attorneys to conduct the examination of the deponent. If two attorneys are designated, the examinations conducted shall not be redundant or repetitive, although clarification of prior testimony may be sought if reasonably calculated to elicit testimony that adds to the substance of prior testimony. No further examination by counsel for MDL 1407 plaintiffs shall be permitted except by agreement or good cause shown. Examination by other parties shall be permitted, but in no event shall it exceed the limitations regarding redundancy or repetition applicable to attorneys conducting the direct examination of the deponent, all as set forth above. Only one attorney may represent the deponent at any given time.

(5) Objections and Directions Not to Answer. Unless otherwise agreed by the parties, and noted on the record, the following stipulations shall apply to all depositions in this action:

(a) Unless otherwise specified by any defendant, an objection by a single defendant shall be deemed an objection by all defendants. However, unless otherwise specified, an instruction not to answer by one defendant should not be deemed an instruction not to answer by all defendants

(b) All objections are reserved until trial or other use of the deposition, except those objections regarding the form of the question or the existence

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of a privilege. Objecting counsel shall say simply the word "objection", and no more, to preserve all objections as to form Only if one of the examining counsel request clarification shall the basis of the objection be stated, and then only the short title of the rule (e.g., "lack of foundation" or "calls for speculation") shall be stated by objecting counsel If the examining attorney requests further clarification, at that attorney's request the deponent shall leave the room while the detailed nature of the objection is clarified and/or discussed

(c) Counsel shall not direct or request that a witness refuse to answer a question, unless that counsel has objected to the question on the ground that the question seeks privileged information, information that the Court has ordered may not be discovered, or a deponent seeks to present a motion to the Court for termination of the deposition on the grounds that it is being conducted in bad faith or in such a manner as unreasonably to annoy, embarrass, or harass the party or the deponent When a privilege is claimed, the witness shall nevertheless answer questions relevant to the existence, extent or waiver of the privilege, such as the date of a communication, who made the statement, to whom and in whose presence the statement was made, other persons to whom the contents of the statement was made, any other person to whom the contents of the statement has been disclosed, and the general subject matter of the communication

(6) Objections to Documents *All objections to the admissibility of* any documents used during the course of a deposition are deemed reserved until the time of trial or use in any dispositive motion No objections to the use of any document are necessary or shall be noted on the record

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(7) **Private Consultations**. Private consultations between deponents and their attorneys during the course of examination are improper except for the purpose of determining whether a privilege should be asserted Unless prohibited by the Court for good cause shown, such conferences may be held during normal recesses and adjournments.

(8) **Disputes During Depositions**. Disputes arising during depositions that cannot be resolved by agreement and that, if not immediately resolved, will significantly disrupt the discovery schedule or require rescheduling of the deposition, or might result in the need to conduct a supplemental deposition, shall be presented to the Court by telephone by calling the Court's Chambers. In the event the Judge is not available, the deposition shall continue as to matters not in dispute with full reservation of rights to continue the examination objected to pending a ruling at the earliest possible time.

If the nature of the dispute would not require the continuance of the deposition pending resolution thereof, the parties may elect to either present the matter to the Court by telephone at a time when the parties and the Court are available, or to present the dispute to the Court in writing. If the parties elect to present the dispute to the Court in writing, each side must submit on one (1) page a summary of its position and any authority relevant to the dispute The Court will issue a prompt ruling, as its schedule permits.

Nothing contained herein shall prohibit examining counsel from continuing with the deposition, filing an appropriate motion with the Court at the conclusion of thereof, and appearing personally before the Court if argument is permitted by the Court

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and counsel deems it necessary. Disputes between the parties should be addressed to this Court rather than to the District Court in which the deposition is being conducted

(9) Copies of Exhibits. A copy of any document about which examining counsel expect to question the deponent should ordinarily be provided to primary counsel for the parties and the deponent at the time presented to the deponent and his/her counsel.

(10) Marking of Deposition Exhibits. Any documents previously produced by defendants or third parties used as exhibits in a deposition shall be referred to by any Bates stamp number(s) appearing on the face of the documents, and a copy thereof shall be included with the original deposition transcript. Documents that do not have Bates stamped number(s) shall be separately marked with sequential exhibit numbers. For example, if the deponent's name is "John Smith", the first exhibit to his deposition that has no identifiable Bates stamp number on its face shall be marked "Smith No. 1 " The same document presented as an exhibit at subsequent depositions shall continue to be referred to as originally marked, and counsel should avoid marking that document with a different exhibit number at any subsequent deposition.

(11) Depositions Pursuant to Rule 30(b)(6). In those instances when the Plaintiffs serve a deposition notice pursuant to Fed. R. Civ P 30(b)(6), the following shall apply (in addition to the foregoing general procedures governing depositions):

(a) Depositions taken pursuant to F.R.C.P. 30(b)(6) will be taken pursuant to the Federal Rules of Civil Procedure and applicable case law.

(b) The party wishing to take the deposition will in good faith describe with reasonable particularity the categories on which the party is requesting

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examination. Within a reasonable period of time after receiving the notice, the party to be deposed will in good faith attempt to inform the discovering party if it believes that multiple witnesses will be necessary to respond to the requested categories of information and to which category each witness will be produced to respond.

(12) Stenographic Recording. A certified Court reporter shall stenographically record all deposition proceedings and testimony. The Court reporter shall administer the oath or affirmation to the deponent. A written transcript by the Court reporter, together with copies of all exhibits marked or referred to during the deposition, shall constitute the official record of the deposition for purposes of Fed. R. Civ P 30(e) (submission to the witness) and 30(f) (filing, exhibits) The transcript shall also contain the name of any attorney and any other person attending the deposition together with the name of his or her firm or organization, business address and, if applicable, the name of the person or organization he or she represents. The court reporter shall be requested to furnish the transcript in electronic form (floppy disks) in text-readable form and hard copy in Min-U-Script format to the representative of plaintiffs conducting the deposition and a designated representative of defendant attending or defending the deposition.

(13) Videotaped Depositions. Any deposition may be videotaped at the request of any party pursuant to notice under the following terms and conditions

(a) All videotaped depositions shall be simultaneously stenographically recorded in accordance with this Order.

(b) The party requesting videotaping of the deposition shall bear the expense of both the videotaping and the stenographic recording. Requests for the

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taxation of these costs and expenses may be made at the conclusion of the litigation in accordance with applicable law.

(c) The operator(s) of the videotape recording equipment shall be subject to the provisions of Fed. R. Civ. p. 28(c). At the commencement of the deposition the operator(s) shall swear or affirm to record the proceedings fairly and accurately.

(d) At the commencement of the deposition, each witness, attorney and any other person attending the deposition shall identify themselves on camera

(e) No attorney or party shall direct instructions to the video operator as to the method of operating the equipment. The video camera operation will be suspended during the deposition only upon stipulation by counsel and "off the record" discussions The video operator shall record on camera the time of suspension and any subsequent reconvening of the deposition.

(f) The deposition will be conducted in a manner to replicate, to the extent feasible, the presentation of evidence at trial Unless physically incapacitated, the deponent shall be seated at a table except when reviewing or presenting demonstrative materials for which a change in position is needed. To the extent practicable, the deposition will be conducted in a neutral setting, against a solid background, with only such lighting as is required for accurate video recording. Lighting, camera angle, lens setting, and field of view will be changed only as necessary to record accurately the natural body movements of the deponent or to portray exhibits and materials used during the deposition. Sound levels will be altered only as

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necessary to record satisfactorily the voices of counsel and the deponent.

(g) If the party noticing the deposition does not intend to convert the videotape to digital form, the videotape operator shall use a counter on the recording equipment and after completion of the deposition shall prepare a log, cross-referenced to counter numbers, that identifies the depositions on the tape at which examination by different counsel begins and ends, at which objections are made and examination resumes, at which exhibits are identified, and at which any interruption of continuous tape-recording occurs, whether for recesses, "off-the-record" discussions, mechanical failure, or otherwise.

(h) After the deposition is completed, the video operator shall certify on camera the correctness, completeness, and accuracy of the videotape recording in the same manner as a stenographic Court reporter, and file a true copy of the video tape, the transcript, and certificate with Liaison Counsel for whomever noticed the deposition.

(i) Technical data, such as recording speeds and other information needed to replay or copy the tape, shall be included on copies of the videotaped deposition.

During the videotaping of a deposition, the questioner may use a two-video camera system with monitors available for use by counsel

(14) Telephonic Depositions. By indicating in its notice of deposition that it wishes to conduct the deposition by telephone, a party shall be deemed to have moved for such an order under Fed R.Civ.P 30(b)(7). Unless an objection is filed and served within ten calendar days after such notice is received, the court shall be deemed

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to have granted the motion Other parties may examine the deponent telephonically or in person. However, all persons present with the deponent shall be identified in the deposition and shall not by word, sign, or otherwise coach or suggest answers to the deponent.

(15) Supplemental Depositions Each party who did not have reasonable notice of a fact deposition and who was not present or represented at the deposition (including parties later added and parties in cases subsequently filed in, removed to, or transferred to this Court) may, within thirty (30) days after filing of the deposition (or, if later, within sixty (60) days after becoming a party in any action which is transferred to this Court), file a motion to conduct a supplemental deposition of the deponent. Each party who wishes to take a supplemental deposition must certify that their attorney has read the prior deposition, and state specifically the areas of inquiry not previously addressed and sought to be pursued in the deposition sought. Within fifteen (15) days of the filing of any such motion, any party may file an opposition to the motion and seek a protective order prohibiting the supplemental deposition on the grounds that the MDL 1407 deposition fully covered the area or areas sought to be explored in the supplemental deposition, that the testimony is not relevant, or any other reason thought valid

(a) No further deposition by any party having received notice of the original deposition will be permitted, except upon order of this Court on good cause shown A showing by the moving party that a supplemental deposition is reasonably calculated to lead to the discovery of admissible evidence necessary to protect the interests of the moving party shall constitute good cause

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(b) If a supplemental deposition is permitted by the Court or unopposed, it shall be treated as the resumption of the deposition originally noticed. During the resumed deposition, the prohibitions regarding redundant or repetitive examination contained herein are fully applicable. The resumed deposition shall be taken at the same location as the initial deposition unless otherwise agreed to by the parties and the deponent.

(16) Copies of Transcripts and Videotapes Subject to any restrictions contained within the Stipulated Confidentiality Order, any party may at its own expense obtain a copy of the videotape and the stenographic transcript by contacting counsel noticing the deposition or the court reporter.

(17) Correction and Signing Depositions. Unless waived by the deponent, the transcript of a deposition, or any portion thereof, shall be submitted to the deponent for correction and signature within thirty (30) days after the completion of the deposition or any portion thereof, unless the Court allows a supplemental deposition pursuant to this Order. If a supplemental deposition is allowed, the transcript thereof shall be submitted to the deponent as soon as it is available for distribution. A deposition transcript, or a transcript of a portion thereof, may be signed by the deponent before any notary within thirty (30) days after the transcript, or any portion thereof, is submitted to the deponent If no corrections are made during this time, the transcript will be presumed accurate.

(18) Use of Depositions. Under the conditions prescribed in Fed R. Civ. P. 32(a) (1) - (4) or as otherwise permitted by the Federal Rules of Evidence, depositions may be used against any party (including parties later added and parties in

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cases subsequently filed in, removed to, or transferred to this Court as part of this litigation) who:

(a) was present or represented at the deposition; or

(b) had reasonable notice thereof, or

(c) within ninety (90) days after the deposition is taken or within one hundred and twenty (120) days after becoming a party to MDL 1407 fails to show *just cause why such deposition should not be used against such party.*

(19) Document Subpoenas to Non-Parties. *Commencing upon entry* of this Order, any party may serve subpoenas on non-parties for the production of documents without testimony pursuant to Fed. R Civ. P. 45.

VI. FACT DISCOVERY OF PLAINTIFFS.

Plaintiffs and Defendants, through their appointed Lead Counsel, are to confer regarding the nature and extent of discovery of plaintiffs in MDL 1407, as well as deadlines and proposed procedures for the conduct of same, and to report back to the Court at the earliest practical time as agreed by Lead Counsel, but no later than thirty (30) days from the date of this Order or the next regularly scheduled Status Conference, whichever first occurs. Plaintiffs, however, shall produce copies of any medical records in their possession referring or related to the injuries alleged in their actions within 30 days of the entry of an Order concerning discovery of plaintiffs or sixty (60) days from *the date of this Order, whichever first occurs.*

VII. EXPERT DISCOVERY

To date, the parties have not agreed whether science and/or expert witness issues involved in this litigation should be resolved in this MDL and, if so, the nature,

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extent and procedures of discovery regarding those issues and/or experts. However, the parties have agreed to continue to attempt to reach an agreement on these issues within the proposed Joint Science Committee, all as proposed in the Joint Submission of the parties dated November 30, 2001. The Joint Science Committee shall meet and shall report to the Court on or before January 11, 2002. At that time, the committee shall provide the Court with a recommended expert discovery schedule, including an expert cutoff date. If the committee cannot reach an agreement, it shall report the disagreement to the Court on January 11, 2002, and shall submit separate proposals by January 18, 2002.

VIII. FAILURE TO COMPLY WITH DISCOVERY REQUESTS.

A party's failure to either produce a relevant document or identify same as withheld pursuant to a privilege may be viewed by the Court as an infraction of its orders, justifying appropriate sanctions. Upon learning of any relevant document(s) which have not been produced or identified, a party is under an obligation to promptly make known the existence of the documents, including the reason for failing to produce same, and submit the document to opposing Lead Counsel, or if withheld under a claim of privilege or protection, identify the documents and the corresponding privilege in the manner described above.

IX. PRODUCTION OF DOCUMENTS FROM PRIOR LITIGATION.

The parties shall meet and confer to resolve disputes over the extent of discovery of documents from prior litigation and shall provide the Court with an agreement by January 11, 2002. If the parties are unable to agree on the extent of discovery, they shall submit separate proposals by January 18, 2002.

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X. CLASS ACTIONS.

A. Economic Injury Class Actions. As of the date of this Order, the Court lifts the stay imposed on potential class certification proceedings. Plaintiffs in *Sims v. The Delaco Company et al.* (C01-1705R) have agreed to voluntarily dismiss their complaint.

(1) Class Certification Discovery and Briefing Schedule. The defendants and plaintiffs shall meet and confer regarding potential stipulations, a discovery plan, and a briefing schedule for the economic injury class certification issue. Counsel shall contact the Court on or before January 7, 2002, to inform the Court of the agreed schedule or, if agreement cannot be reached, to present separate proposals

(2) Merits Discovery and Other Deadlines. Non-expert merits discovery shall end on December 31, 2002. Merits discovery in the class actions shall be coordinated with merits discovery in the personal injury actions, so that no duplicative discovery shall be taken and so that discovery taken in non-MDL cases shall be applicable in the class actions to the same extent that it is applicable in the MDL personal injury actions. To the extent that relevant merits discovery commences in the personal injury actions before the Court rules on the class certification issue in the economic injury class actions, the parties in the economic injury class actions can and shall participate so as to avoid duplicative discovery

A schedule for expert discovery, Daubert motions, summary judgment motions and remaining dates applicable in the class action cases shall be set at a later date.

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B. Personal Injury Class Actions. *Defendants shall file a motion to strike* class allegations on or before January 25, 2002. If plaintiffs contend discovery is necessary before they can respond to defendants' motion, plaintiffs shall file their motion for discovery by February 1, 2002 The motion should include the specific areas of discovery required and the reason discovery is needed, as well as proposed dates for discovery. Defendants may file a response to the discovery motion by February 8, 2002. No reply will be filed.

If the Court denies the motion for discovery, plaintiffs shall file their opposition to defendants' motion to strike class allegations within seven (7) days of receiving the Court's decision. The defendants' reply shall be filed within fourteen (14) days of receiving the opposition, and any sur-reply by the plaintiffs shall be due fourteen (14) days after receiving the reply. If the Court grants the motion for discovery, the parties shall follow the briefing schedule provided by the Court in that order

If the plaintiffs do not bring a motion for discovery, plaintiffs shall file their opposition to the motion to strike class allegations on February 28, 2002. Defendants shall file their reply on March 15, 2002, and plaintiff shall file any sur-reply by March 29, 2002.

XI. OTHER PROVISIONS

A. Individual Appointment of Plaintiff Counsel. The Court has appointed *specific plaintiffs counsel to various positions on the expectation of their personal* contribution to the work of the Plaintiffs' Lead Counsel, Steering Committee ("PSC") and other Committees and to the furtherance of the completion of the MDL portion of PPA litigation. For this reason, the Court will look to the Lead Counsel and the individual

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members of the Plaintiffs' various committees to satisfy the goals that the Court expects the PSC and the various Committees to achieve. The Court will likewise consider the contribution of each member of the PSC and its Committee members when the Court is called upon to determine appropriate compensation for service on the PSC and its Committees. While the Court recognizes that each of the above members will require the assistance of partners, colleagues, paralegals, support staff and others in the fulfillment of their committee assignments, the Court will expect the individual members to be responsible for the ultimate outcome of the activities performed by the PSC and its Committees.

B. Time and Expense Keeping. Counsel who anticipate seeking an award of attorney's fees and reimbursement of expenditures shall comply with the directives contained in the Manual for Complex Litigation, Third, §41.32 regarding the maintenance of contemporaneous records reflecting the services performed and the expenses incurred. The Court will address, in a future CMO, the extent to which an assessment will be ordered in this matter.

C. Privileges Preserved. No communication by and between the respective parties' Lead Counsel, their Liaison Counsel and/or members of their respective Committees shall constitute a waiver of any privilege or protection to which it would otherwise be entitled.

XII. NEXT STATUS CONFERENCE.

The next status conference is scheduled for _____. At the next and all future status conferences, the parties are to provide to the Court within five (5) business days before each status conference an agreed upon agenda for the

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conference, and shall provide a brief (1-2 paragraph) summary of the party positions as to any disputed issues.

XIII. PERSONS BOUND BY THIS ORDER.

This Order shall be binding on all persons with cases docketed in MDL 1407.

The Honorable Barbara Jacobs Rothstein
United States District Judge

DATED this 29th day of January, 2002

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THE HONORABLE BARBARA J. ROTHSTEIN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE: PHENYLPROPANOLAMINE (PPA) PRODUCTS LIABILITY LITIGATION, This document relates to all actions	MDL Docket No. 1407 PLAINTIFFS' MASTER FIRST SET OF INTERROGATORIES

Pursuant to Rule 33 of the Federal Rules of Civil Procedure, the following Interrogatories are propounded to Defendant, to be answered separately and fully, in writing, and under oath as prescribed by said rules within 30 days, or at such other time as ordered by the Court.

INSTRUCTIONS

1. Each Interrogatory set forth herein refers to information in the custody, control, and possession of Defendant or known to Defendant, as well as in the custody, control, and possession of or known to Defendant's counsel, representatives, agents,

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servants, investigators, and consultants, and their counsel, employees, representatives, agents, servants, investigators and consultants.

2. If there is a claim of privilege with respect to any response, please provide a privilege log that states the nature of the information being withheld, the general subject matter of the withheld information, a statement of the facts constituting the basis for any claim of privilege, and the specific basis on which the privilege is claimed.

3. The term "person" is used in its broadest possible sense and includes a natural person, corporation, firm, association, organization, business, trust, corporation, governmental or other public entity.

4. When asked to identify a person, or if the response involves a person, for each person please state the full name, business title, and the last known home and business addresses and telephone numbers.

5. When asked to identify a communication, or if an answer involves a communication, for each communication please state the parties to the communication, the nature of the communication (e.g. written, oral, recorded), witnesses to the communication, and the substance of the communication.

6. When asked to identify a document, or when an answer involves a document, please state the person who wrote, composed or created the document, the intended recipients, the date originated, the date sent, the date received, all persons having copies of the document, and the subject matter and content. In lieu of identifying a document, a copy of the document can be attached to these responses.

7. For each Interrogatory, identify any persons providing information, and state whether the response is based on the personal knowledge of the person providing the

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information. If the response is not based on the personal knowledge of the person providing the information, identify the sources (e.g. persons, documents) of that information.

8. If information contrary to that provided in an answer was provided by any person to the person providing the answer, or to your attorneys, identify each person providing conflicting information, state the conflicting information, and state the reasons the conflicting information was not relied upon.

9. For each answer, identify all documents that you believe support your response.

10. These Interrogatories shall be deemed continuing, to the full extent required or permitted under the Federal Rules of Civil Procedure, so as to require supplementary responses as soon as practical after you receive information which renders any of your answers to these Interrogatories incomplete or inaccurate.

DEFINITIONS

1. "PPA" means phenylpropanolamine and "PPA product" means any product containing PPA

2. "FDA" means the United States Food & Drug Administration, any committee, subcommittee or advisory committee thereto, and any person, employee or agent acting as a representative thereof.

3. "Foreign Government Regulatory Authority" means any agency, committee, subcommittee or advisory committee of any government other than the United States of America, which bears responsibility or exercises authority over the manufacture, distribution, labeling, sale and/or marketing of pharmaceutical products or

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human health in any jurisdiction, and any employee or agent acting as a representative thereof.

4. "Defendant", "You" and "Your" refers to every corporation or other person or entity upon whom plaintiffs serve this set of discovery requests and also includes every predecessor in interest of each such company, its successor(s) in interest, and every company affiliated with each such company by common ownership or control.

5. As used throughout these Interrogatories, the term "document" or any similar term is used in its broadest possible sense and shall include, but not be limited to any original, reproduction or copy, and nonidentical copy (i.e., copy with marginal notes, deletions, etc.) of any kind of written, printed, typed, electronically created or stored, or other graphic matter of any type, documentary material, or drafts thereof, including, but not limited to, any correspondence, memoranda, interoffice or intra-office communications, notes, diaries, journals, calendars, contract documents, publications, calculations, estimates, vouchers, minutes of meetings, invoices, reports, studies, computer tapes, computer disks, computer cards, computer files, e-mails, photographs, negatives, slides, dictation belts, voice tapes, telegrams, notes of telephone conversations and notes of any oral communications

6. As used throughout these Interrogatories, the term "communication" is intended in its broadest sense and refers to any oral, written, video, photographic, or other means utilized to express an idea, thought, or information from one person to another, or among persons.

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INTERROGATORIES

1. State the corporate name of Defendant, any name under which Defendant does business, and the identity and title of all persons who participated in the preparation of these interrogatory responses, excluding counsel.

2. State the division(s), subsidiary or operating unit(s) responsible for the following regarding PPA products:

a. Product design;

b. Pre-clinical testing;

c. Clinical testing;

d. Regulatory approval and compliance;

e Manufacturing;

f. Marketing;

g. Labeling;

h. Promotion; and

i. Distribution.

3. Identify the individuals with supervisory and/or managerial responsibilities for the following regarding PPA products:

a. Product design;

b. Pre-clinical testing;

c. Clinical testing;

d. Regulatory approval and compliance;

e. Manufacturing;

f. Marketing;

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g. Labeling;

h. Promotion; and

i. Distribution.

4. Identify each PPA product you manufacture or distribute and for each such product, identify the individuals with supervisory and/or managerial responsibilities for:

a. Monitoring adverse reactions;

b. Monitoring the medical literature regarding PPA safety issues;

c. Determining whether the labeling for the product needed to be changed and, if so, implementing any labeling change;

d. Determining whether PPA should be removed from the product and if so, implementing any reformulation of the product;

e. Interacting or communicating with the Consumer Healthcare Products Association ("CHPA") or the Nonprescription Drug Manufacturer's Association ("NDMA") regarding the safety of PPA;

f. Interacting or communicating with other manufacturers of PPA products regarding the safety of PPA;

g. Interacting or communicating with FDA regarding the safety of PPA;

h. Interacting or communicating with any other State, Federal or Foreign regulatory agency regarding the safety of PPA;

i. Conducting any testing in humans or animals regarding the safety of PPA;

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j. Contracting with any other person or entity to perform any testing in humans or animals regarding the safety of PPA; and

k. Communicating or interacting with any person or entity that conducted studies regarding the safety of PPA.

5. Identify and describe any testing done by or on behalf of defendant to determine whether the ingestion of PPA is associated with an increased risk of stroke.

6. Ranging from the Chief Executive Officer to the most junior managerial level of your company, identify and describe the chain of command since 1990 for insuring that the labeling of PPA products adequately warned consumers of the risks of PPA products.

7. Ranging from the Chief Executive Officer to the most junior managerial level of your company, identify and describe the chain of command since 1990 for making the decision as to whether PPA should be removed from any of your products for safety reasons.

8. Identify each over-the-counter consumer product containing PPA marketed by your company and for each product state:

a. The dollar amount spent on all advertising for each such product in each of the years since 1990;

b. The dollar sales of each such product in each of the years since 1990;

c. The gross profit derived from the sales of each such product in each of the years since 1990; and

d. The net profit derived from the sales of each such product in each of the years since 1990.

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9. State whether you have re-formulated any of your PPA products such that they do not now contain PPA and, if so, state:

a. The ingredient which was used to replace PPA; and

b. The cost of reformulating the product without PPA.

10. State whether at any time between January 1, 1990 and January 1, 2000 you considered removing PPA from any of your products and, if so, identify:

a. Any individuals who recommended removing PPA from any of your products;

b. Any individuals who made the decision to remove or not remove PPA from any of your products; and

c. Any documents relating or referring to any proposed removal of PPA from any of your products.

11. State whether at any time between January 1, 1990 and January 1, 2000 you analyzed whether the removal of PPA from any of your products would impact your market share, dollar sales or the cost of production for such product and if so:

a. Identify the individuals who performed such analyses;

b. Identify the individuals who were informed of the results of such analyses; and

c. Identify any documents relating or referring to such analyses.

12. As to any government investigation, regulatory action, indictment, information, or criminal charge which has ever been made or brought against Defendant in regard to the promotion, marketing, sale or distribution of any of its drug products, state:

a. The Product involved;

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b. The court, agency and jurisdiction involved;

c. The filing date;

d. The time period at issue;

e. The current status or disposition of the investigation, regulatory action or criminal charge; and

f Any claim, file, court number or other identifying information regarding the investigation, regulatory action or charge.

13. State whether any of your PPA products were marketed outside of the United States. If so, state:

a. The location(s) outside of the United States where each was marketed;

b. The period of time when your PPA products were marketed, sold and/or distributed in each such location outside of the United States;

c. The indications, contraindications and risks reflected in the labeling which accompanied your PPA products when they were marketed in each such location outside of the United States (in English);

d. Whether any foreign government regulatory authority took any action to prohibit or limit the manufacture, sale, distribution or use of your PPA products, identifying the agency involved and the action taken; and

e. Whether any foreign government regulatory authority requested you or any other distributor of PPA products to withdraw such products from the market or restrict their use.

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14. With respect to any case of hemorrhagic stroke in any person using any of your PPA products:

a. State the date on which you first became aware that any consumer using any of your PPA products suffered a hemorrhagic stroke after using your product;

b. State the total number of reports of hemorrhagic stroke reported in consumers using your PPA products;

c. Identify each person who furnished and/or received such information;

d. State whether each report of such information was provided to the FDA and, if so,when; and

e. Identify all documents relating, referring to or embodying such information and/or its reporting to the FDA.

15. Identify all documents in your possession custody or control that relate, refer to or embody any studies, tests, analyses or research, including any interim or preliminary reports or data from such studies, conducted by any person or entity regarding hemorrhagic stroke in consumers using any PPA product.

16. State the total amount of insurance which you believe may be available to satisfy any claims which have been made in the past and which may be made in the future against you, your predecessors, successors, and assigns as a result of the use of PPA products. This requires, without limitation, that you:

a. Identify each and every general liability, comprehensive general liability, advertising liability or product liability policy (and every other policy which you believe may provide coverage to any personal injury claim

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asserted in this litigation) that you purchased or on which you are a named insured (including policies purchased by related corporate entities), including all excess layers and/or umbrella policies, for a minimum of the years 1990 through 2000, or for any additional years in which you manufactured or distributed PPA products, including the policy number, name and address of the insurer who issued the insurance policy and indicate any self-insured retention,

b. State the type of coverage provided by each such policy (e.g., claims made, occurrence based, etc.);

c. State the limits of liability per claim and in the aggregate for each such policy;

d. State the effective dates of each such policy;

e. State whether each such policy is consuming (e.g., whether payments of counsel fees and defense costs consume the available limits of liability);

f. State the amounts which have been paid under each such policy and the extent to which such payments have exhausted the aggregate limits of coverage provided by each such policy;

g. State the name of your risk manager or person most knowledgeable about your insurance coverage for the years 1990 through 2000;

h. State the name, address and telephone number of your insurance broker(s) for the years 1990 through 2000 for the insurance identified in response to sub-part (a) above;

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i. State whether or not you have tendered any claims or provided notice in this litigation to any insurer or any insurance policy other than those identified in sub-part (a) above. If so, include the name and address of the insurer and the policy number and, if the policy is issued to anyone other than yourself, the insured under the policy; and

j State whether any carrier has notified you of any reservation of rights, and, if so, identify all documents relating thereto.

17. State the full corporate name and principal address of each entity with whom you are affiliated through common ownership and control. With respect to each such entity, describe its past and present role in connection with the design, testing, manufacture, marketing, sale and/or distribution of PPA products.

18. Describe your document retention/destruction policies and procedures from 1985 through the present including:

a. What documents (including computer files) are routinely discarded and when; and

b. How and where you file safety related documents.

19. For the period January 1, 1990 through January 1, 2000, please state if you modified the formulation of your PPA products or their labeling due to any concerns about high blood pressure or stroke. If so,

a. Describe each such modification;

b. State the dates on which you first notified the FDA of the modification;

c. State the dates on which each labeling change was implemented in distributed product;

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d. State whether you undertook any efforts to notify or educate consumers about any such re-formulation or labeling change; and

e. Identify any documents relating or referring to the subject matter of any of the previous subparts of this interrogatory.

20. Identify and describe all indemnity agreements, agreements to assume liability, agreements to assume the defense, or any other such agreements between you, your insurer and any other person regarding any claims pertaining to the manufacture and distribution of any of your PPA products.

21. Provide the following information about your company:

a. The address of your principal place of business;

b. The identity, by name and title, of your current corporate officers;

c. The identity of your current board of directors;

d. State whether your company is owned in material part (50% or greater) by any other persons or entities and, if so, identify the owners and their ownership interests;

e. Briefly describe your involvement with any other corporation involved the manufacture and distribution of PPA products; and

f. Provide the most current financial data available regarding your company's:

i. Gross sales;

ii. Net income;

iii. Total assets;

iv. Cash;

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v. Current assets;

vi. Current liabilities;

vii. Equity;

viii. Long-term debt; and

ix. Short term debt.

g. Identify the individual most knowledgeable regarding your financial status.

h. Identify the individual most knowledgeable regarding your insurance coverage.

22. Please state the number of lawsuits presently pending against you and/or any of your subsidiaries involving any of your PPA products. For each such lawsuit, please give the following information:

a. The place of jurisdiction, case number and complete caption; and

b. The name, firm name, address and telephone number of the lawyer(s) who have filed the case on behalf of each plaintiff

23. Please state the number of lawsuits that have been settled or dismissed against you and/or any of your subsidiaries involving any of your PPA products. For each such lawsuit, please give the following information:

a. The place of jurisdiction, case number and complete caption;

b. The name, firm name, address and telephone number of the lawyer(s) who filed the case on behalf of each plaintiff; and

d. The date on which the lawsuit the lawsuit was settled.

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24. State whether between 1990 – 2000 your company had any written codes of conduct or ethical standards regarding the marketing and labeling of drug products and, if so:

a. Identify any documents that relate, refer to or embody such codes of conduct or ethical standards;

b. State whether your company had any department or office that was charged with the responsibility for determining whether your company complied with such codes of conduct or ethical standards; and

c. Identify any officers and/or employees with managerial or supervisory responsibility for determining whether the corporation's conduct was in compliance with such codes of conduct or ethical standards.

25. State whether between 1990 – 2000 your company belonged to any pharmaceuctical manufacturer's trade associations or other groups that had codes of conduct or ethical standards regarding the marketing and labeling of drug products and, if so:

a. Identify any documents that relate, refer to or embody such codes of conduct or ethical standards;

b. State whether your company had any department or office that was charged with the responsibility for determining whether your company complied with such codes of conduct or ethical standards; and

c. Identify any officers and/or employees with managerial or supervisory responsibility for determining whether the corporation's

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conduct was in compliance with such codes of conduct or ethical standards.

Respectfully Submitted,

Levinson Friedman, P.S.

Lance E. Palmer, Esq.
WSBA #18141
Plaintiffs' Liaison Counsel

Signed and submitted on behalf of, and approval of, the individuals listed below

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THE HONORABLE BARBARA J. ROTHSTEIN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE: PHENYLPROPANOLAMINE (PPA) PRODUCTS LIABILITY LITIGATION, This document relates to all actions	MDL Docket No. 1407 PLAINTIFFS' MASTER FIRST SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, plaintiffs respectfully request that Defendant produce the following documents and tangible things for inspection and copying at the office of liaison counsel for plaintiffs within thirty (30) days of service of these requests, or at such other time as ordered by the Court.

INSTRUCTIONS

(a) Each Request set forth herein refers to documents in the custody, control, and possession of Defendant or known to Defendant, as well as in the custody, control, and possession of or known to Defendant's counsel, representatives, agents, servants,

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investigators, and consultants, and unless otherwise privileged, their counsel, employees, representatives, agents, servants, investigators and consultants.

(b) With respect to any of the requested documents, if any such document is unavailable, because it was lost or destroyed by Defendant or its agents, or for any other reason, after fully identifying the document, state when and where it was destroyed or is otherwise unavailable, the name and address of the person who destroyed it, the name and address of the person(s) who directed, approved, or knew of its destruction, and the name and address of the person(s) who has knowledge of such document.

(c) If there is a claim of privilege with respect to any document requested, please identify every such document in the response, and include in the identification a description of the document, the date of the document, the names of the addressees and addressors, the identity and address of every person to whom a copy was given or communicated, the general subject matter of the document, a statement of the facts constituting the basis for any claim of privilege, and the specific basis on which the privilege is claimed.

(d) If you cannot produce documents for any other reason, respond to the extent possible, stating your reasons for your inability to respond in full.

(e) The documents produced responsive to these Requests should be numbered or stamped in such a fashion as to identify the individual custodian from whose files the documents were produced. Alternatively, Defendant may, contemporaneously with the production of documents responsive to these Requests,

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provide a list identifying which particular documents were produced from particular individuals' files.

(f) These Requests shall be deemed continuing, to the full extent required or permitted under the Federal Rules of Civil Procedure, so as to require supplementary production when Defendant obtains access, custody, possession or control of any document not previously produced, which is responsive to any of these Requests.

(g) The headings used herein are for guidance and clarity only and should not be deemed to restrict or broaden any request.

DEFINITIONS

(a) "PPA" means phenylpropanolamine and "PPA Products" means any products phenylpropanolamine.

(b) "FDA" means the United States Food & Drug Administration, any committee, subcommittee or advisory committee thereto, and any person, employee or agent acting as a representative thereof.

(c) "Foreign Government Regulatory Authority" means any agency, committee, subcommittee or advisory committee of any government other than the United States of America, which bears responsibility or exercises authority over the manufacture, distribution, labeling, sale and/or marketing of pharmaceutical products in any jurisdiction, and any employee or agent acting as a representative thereof.

(d) "Defendant", "You" and "Your" refers to every corporation or other person or entity upon whom plaintiffs serve this set of discovery requests, and also includes

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every predecessor in interest of each such company, its successor(s) in interest, and every company affiliated with each such company by common ownership or control.

(e) As used throughout this Request for Production of Documents, the term "document" or any similar term is used in its broadest possible sense and shall include, but not be limited to any original, reproduction or copy, and non-identical copy (i.e , copy with marginal notes, deletions, etc.) of any kind of written, printed, typed, electronically created or stored, or other graphic matter of any type, documentary material, or drafts thereof, including, but not limited to, any correspondence, memoranda, interoffice or intra-office communications, notes, diaries, journals, calendars, contract documents, publications, calculations, estimates, vouchers, minutes of meetings, invoices, reports, studies, computer tapes, computer disks, computer cards, computer files, e-mails, photographs, negatives, slides, dictation belts, voice tapes, telegrams, notes of telephone conversations and notes of any oral communications.

DOCUMENT REQUESTS

A. CORPORATE DATA

1. Produce:

a. Each and every general liability, comprehensive general liability, advertising liability or product liability insurance policy (and any other insurance policy which you believe may provide coverage for the personal injury claims asserted in this litigation that you purchased or on which you are a named insured (including policies purchased by related corporate entities), including all excess layers, for the years 1990 through 2000 inclusive;

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b. Any charts or schedules of layers of insurance or self-insured retention for any of the respective years of coverage; and

c. Any documents relating or referring to any disputes or reservations of rights as to coverage.

2. Produce all documents relating, referring to or embodying any indemnity agreements, agreements to assume liability, agreements to assume the defense and joint defense agreements made by Defendant, insurers for Defendant, or any other entities that may be financially affected by any of the claims asserted in this litigation.

3. Produce all documents relating, referring to or embodying all licenses, contracts, royalty arrangements or other agreements made by Defendant and any other entity related to the transfer of responsibility for the sale, marketing, manufacturing , testing or compliance with FDA regulations for any of your PPA Products.

4. Produce:

a. All documents reflecting your year end financial statements for the years 1990- 2000;

b. Quarterly reports for the current fiscal year [this includes 10-Ks and 10-Qs for publicly traded companies]; and

c. All of your filings with the National Association of Securities Dealers for the years 1990-2000.

5. Produce your annual reports for the years 1990-2000.

6. Produce all of your document retention or document destruction policies in effect for the years 1990-2000 and all documents which discuss or refer thereto.

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7. Produce Defendant's articles of incorporation, by-laws, and any amendments thereto.

8. For each year between 1990-2000 in which defendant designed, tested, manufactured, sold, marketed, licensed or distributed a PPA Product, produce all documents relating, referring to or embodying:

a. General corporate organizational charts;

b. Sales department organizational charts;

c. Marketing department organizational charts;

d. Research and development department organizational charts; and

e. Medical department organizational charts

9. Produce any documents reflecting:

a All corporate officers for the last five years;

b. All members of the Board of Directors for the last five years;

c. All persons or entities which owned 5% or more of Defendant's common stock for the last five years; and

d. Annual organization charts for any entity which owned more than 5% of Defendant's common stock during the last five years.

10. As to any entity with which you are affiliated through common ownership and control that is involved in the manufacture, testing, marketing, licensing, sale or distribution of a PPA Product, produce all documents which describe in any way the responsibilities that each such entity has in regard to any PPA Product.

11. Produce all indices, including but not limited to computer print-outs, listing the name, case caption, attorney and/or status of any lawsuit filed against Defendant

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regarding any PPA Product, including cases which have been dismissed, settled, withdrawn or tried to verdict and produce documents reflecting the plaintiffs' attorneys' address, fax and telephone numbers.

12. Produce all documents relating, referring to or embodying minutes of all Board of Directors meetings which in any way refer to the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product.

13. Produce any documents relating, referring to or embodying notice of claims, claims projections, loss estimates or risk management related to PPA Products.

14. Produce all documents relating, referring to or embodying any correspondence, communications, contracts or other discussions of any kind between Defendant, its agents or any party acting on Defendant's behalf, and any other drug company concerning the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product.

15. Produce all documents relating, referring to or embodying any codes of conduct or ethical standards promulgated, adopted or followed by Defendant between 1990-2000 with respect to the marketing or labeling of drug products.

16. Produce all documents relating, referring to or embodying any codes of conduct or ethical standards with respect to the marketing or labeling of drug products that were promulgated or adopted by any trade organization of which Defendant was a member between 1990-2000.

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B. FDA AND GOVERNMENT REGULATORY DOCUMENTS

17. Produce all documents relating, referring to or embodying communications between Defendant or any agent or consultant of Defendant, and the FDA, regarding the , vasculitis, vasospasm or hypertension with the use of any PPA Product.

18. Produce all documents concerning any internal FDA meetings, FDA Advisory Panel meetings, meetings between FDA and any manufacturers of PPA Products and meetings between FDA and any trade organization regarding the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product, including but not limited to:

a. All documents relating or referring to any communications between Defendant (or any agent or consultant of Defendant), and the FDA or any Advisory Panel Member regarding the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product;

b. All documents relating or referring to any financial contributions or other items of value provided to Panel Members or their institutions/ organizations; and

c. All documents relating, referring to or embodying minutes of meetings, agendas, dossiers, submissions, test summaries, internal memoranda regarding strategies and issues, Questions and Answers, scheduling, or any other documents concerning such meetings, the submissions thereto, or the topic(s) discussed.

19. Produce:

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a. Complete files for all adverse reaction reports concerning the occurrence of stroke with the use of any PPA Product in the United States.

b. All summaries (including but not limited to computerized data), analysis or interpretations of any such adverse reaction report(s); and

c. All documents which discuss or refer to any adverse reaction report, or any summary, analysis or interpretation thereof.

20 Produce.

a. All documents relating or referring to adverse drug reactions or alleged adverse drug reactions concerning reports of stroke with the use of any PPA Product which occurred in any country other than the United States;

b. All documents relating or referring to or embodying summaries, computerized data, analysis, or interpretation of said reports;

c. All documents relating, referring or embodying the submission of said reports to any government regulatory authority, whether FDA or foreign,

d All documents relating or referring to the failure to submit such reports to any government regulatory authority, whether FDA or foreign; and

e. Produce all documents which relate, refer to or embody any such incidents or reports.

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21. Produce all documents relating, referring to or embodying any communication with or submissions to the FDA or any foreign government regulatory authorities regarding the regulation, approval, safety or testing of any PPA Product in connection with the risk or occurrence of stroke, vasculitis, vasospasm or hypertension.

22. Produce all documents relating, referring to or embodying any communication with or submissions to the FDA or any foreign government regulatory authority regarding the recall of any PPA Product or the removal of PPA from the product due to the risk or occurrence of stroke, vasculitis, vasospasm or hypertension.

23. Produce:

a. All documents relating, referring to embodying any communications between Defendant and any physician, pharmacist or other health care provider regarding any PPA Product, including but not limited to all documents, including drafts, of any Dear Doctor or Dear Pharmacist letters concerning any PPA Product; and

b. All documents relating, referring to or embodying any communications with the FDA or any foreign government regulatory authority regarding the content or approval of such communications.

24. Produce all documents relating, referring to or embodying any information received by Defendant from any physician in regard to the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product.

25. Produce all documents relating, referring to or embodying any discussions, negotiations or contracts to engage any third party to represent Defendant's interests before the FDA or any foreign government regulatory authority, or

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any Committee or subcommittee thereof, in regard to the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product, including but not limited to retainer agreements or consultant agreements.

26. Produce all documents relating, referring to or embodying any discussion or submission between Defendant and any state government regulatory agency or any state medical society concerning the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product.

C. PRODUCT TESTING

27. Produce all documents relating, referring to or embodying any pre-clinical studies or testing of any PPA Product to assess the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of PPA, including but not limited to test protocols, data compilations, laboratory notebooks, summaries of results, drafts of reports, interim reports, final reports, published articles, financial renumeration, engagement of consultants/investigators, internal memoranda and submissions of data to the FDA or any Foreign Government Regulatory Authorities.

28. Produce all documents relating, referring to or embodying any clinical studies or testing to assess the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product, including but not limited to test protocols, data compilations, laboratory notebooks, summaries of results, drafts of reports, interim reports, final reports, published articles, financial renumeration, engagement of investigators, internal memoranda and submissions of data to the FDA or any Foreign Government Regulatory Authorities.

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29. Produce all documents relating, referring to or embodying any epidemiology studies assessing the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with any PPA Product, including but not limited to test protocols, data compilations, summaries of results, drafts of reports, interim reports, final reports, published articles, financial renumeration, engagement of investigators, internal memoranda and submissions of data to the FDA or any Foreign Government Regulatory Authorities.

30. Produce all documents concerning any receipt, discussion, studies, analysis or review of clinical experience reports for any PPA Product to assess the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of PPA, including but not limited to formally submitted adverse reaction reports, communications (whether written or oral) concerning case reports, published clinical experience reports, or any other such report made known to Defendant.

31. Produce all documents:

a. Relating, referring to or embodying studies assessing the risk or occurrence of stroke with any PPA Product conducted by any third parties, including but not limited to those funded by trade groups or associations;

b. Relating, referring to or embodying Defendant's review, analysis, investigation or interpretation of said results; and

c. Relating, referring to or embodying any attempts by Defendant to submit said data to the FDA or any Foreign Government Regulatory Authority.

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32. Produce all documents relating, referring to or embodying any financial support by Defendant to any other person or entity conducting any study or analysis of the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA product.

33. Produce all documents relating, referring to or embodying any decision on the part of Defendant not to provide any financial support for any studies or analyses of the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA product.

34. Produce all documents relating, referring to or embodying any testing of any PPA Product to assess the risk or occurrence of stroke, vasculitis, vasospasm or hypertension which defendant did not complete, did not publish, or did not submit to the FDA or any Foreign Government Regulatory Authority.

35. As to any clinical, animal or other study currently sponsored by, financed by, undertaken by, or suggested by Defendant to assess the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with any PPA Product, provide all documents concerning said study, including but not limited to engagement letters, contracts, protocols, status reports, raw data, summary of findings, internal memorandum, drafts of reports, interim reports, final reports, manuscripts, submissions to publishers, submissions to FDA or any Foreign Government Regulatory Authority, or discussions, communications or analysis of the current or final results.

36. Produce:

a. All documents relating, referring to or embodying a bibliography of articles or reports concerning the risk or occurrence of stroke, vasculitis,

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vasospasm or hypertension with any PPA Product, including but not limited to monographs, presentations, letters to the editor, abstracts, and any other published reports; and

b. Copies of each such article or report in Defendant's possession.

37. Produce all documents relating, referring to or embodying any unpublished reports, speeches, data compilations, clinical observations or other communications concerning the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with any PPA Product.

38. Produce all documents relating, referring to or embodying any laboratory testing and/or studies regarding the pharmacology, pharmacokinetics and/or biochemical properties of any PPA Product that were undertaken to assess the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of such product.

39. Produce all documents relating, referring to or embodying any communications by Defendant with any publisher, editor, author, reporter or employee of or for any lay, scientific, medical or news publication or any free lance writer concerning the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with any PPA Product.

40. Produce all documents relating, referring to or embodying any efforts by Defendant to study, monitor or test for the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of a PPA Product, either alone or in combination with any other drug.

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41. Produce all documents that relate, refer to or embody any communication, report or inquiry between Defendant and the Centers or Disease Control in regard to the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product.

42. Produce all documents that relate, refer to or embody any communication, report or inquiry between Defendant and the National Institutes of Health in regard to the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product.

43. Produce all documents that relate, refer to or embody any communication, report or inquiry between Defendant and the World Health Organization in regard to the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product.

44. Produce all documents that relate, refer to or embody any communication, report or inquiry between Defendant and the Drug Enforcement Agency (DEA) in regard to the risk or occurrence stroke with the use of any PPA Product.

D. PRODUCT RECALL

45. Produce all documents relating, referring to or embodying any communications with the FDA or any foreign government regulatory authority regarding any discussion or suggestion that Defendant eliminate PPA from any of its products or withdraw any PPA Product from the market.

46. Produce all documents relating or referring to any discussion, suggestion or study of whether PPA should be removed from any products or whether any PPA Product should be withdrawn temporarily or permanently from the market, including but

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not limited to internal memorandum, notes of conversations, communications with the FDA or any Foreign Government Regulatory Authority, and communications with other manufacturers, licensors, licensees, distributors, or marketers.

47. Produce all documents regarding any discussion, suggestion or study of whether any current or pending, approved or unapproved NDA, ANDA, or IND for any PPA Product should be withdrawn or suspended temporarily or permanently due to safety concerns, including but not limited to internal memorandum, notes of conversations, communications with the FDA or other Foreign Government Regulatory Authority, and communications with other manufacturers, licensors, licensees, distributors, or marketers.

48. Produce all documents, (including but not limited to drafts) concerning recall notices, dear doctor letters, letters to physicians, pharmacists or other health care providers, newspaper or other print advertisements, press releases, questions and answers or other public statements regarding the recall of any PPA Product or the removal of PPA from any product.

49. Produce all documents relating, referring to or embodying the hiring or retention by Defendant or by any other person or entity acting on Defendant's behalf, of any public relations firm or any law firm specializing in drug regulatory practices to participate in, orchestrate, organize or otherwise direct the recall effort for any Related Products and produce all documents regarding said engagement, including but not limited to questions and answers, talk papers, scripts for telephone calls, creation of special advisory or consulting boards, gestures to demonstrate concern for victims,

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donations to causes important to victims, retention of scientific or medical researchers, advisors or experts and other such public relations strategies.

50. Produce all documents relating, referring to or embodying the retention of persons in any medical discipline to study, assess or analyze the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product by or on behalf of Defendant, whether retained directly by Defendant or otherwise.

51. Produce all documents relating, referring to or embodying any analysis of the actual or anticipated impact of the reformulation of any of your PPA products to remove PPA from the product on:

a. The cost of producing such reformulated product;

b. The market share of such reformulated product;

c. The dollar sales of such reformulated product; and

d. Consumer preference or satisfaction with such reformulated product.

E. LABELING

52. Produce all documents relating, referring to or embodying any labeling, including drafts and revisions thereto, ever generated for each PPA Product tested, licensed, manufactured, marketed or distributed by Defendant.

53. As to each change in the PPA Product labeling, produce all documents relating, referring to or embodying said label change.

54. Produce all documents relating, referring to or embodying communications by Defendant or other materials distributed by Defendant to physicians, pharmacists or consumers regarding any change in the labeling or recommendations for use of any PPA Product, including but not limited to Dear Doctor letters.

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55. Produce all documents relating, referring to or embodying any communications with the FDA or any Foreign Government Regulatory Authority regarding changes in the label or recommendations for use of any PPA Product.

56. Produce all documents, including but not limited to internal memorandum, minutes of meetings, and draft proposals, regarding any consideration, discussion, decision or attempt to revise any label or recommendations for use of any PPA Product.

57. Produce all documents relating, referring to or embodying information published in any PDR concerning any PPA Product, and produce all documents relating, referring to or embodying revisions, alterations or discussions of PDR data.

58. Produce all documents relating, referring to or embodying materials provided to consumers upon purchase of any PPA Product, such as package inserts, instructions or warnings included within the packaging and produce all documents relating, referring to or embodying drafts of said documents, discussions of said documents or revisions or alterations thereto.

F. MARKETING

59. Produce:

a. An exemplar color copy of each direct consumer advertisement for any PPA Product;

b. All documents relating or referring to the issue of whether a warning about the risk or occurrence of stroke, vasculitis, vasospasm or hypertensions should be mentioned in any such advertisements.

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60. Produce:

a. All documents relating, referring to or embodying any press releases or public relations material for any PPA Product that relate or refer to the risk or occurrence of strokes with the use of such products; and

b. All documents relating, referring to or embodying any drafts, discussions, FDA approvals or revisions of said information.

61. Produce:

a. Exemplars of any videotapes or other visual aids created by Defendant to advertise and promote the use of any PPA Product; and

b. All documents relating or referring to the issue of whether a warning about the risk or occurrence of stroke, vasculitis, vasospasm or hypertensions should be mentioned in any such videotapes or visual aids.

62. Produce all documents relating, referring to or embodying sponsorship, financial support, contribution of product, consultation agreements, or other items of value provided to or for any person studying the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product, either alone or in combination with another drug.

63. Produce all documents relating, referring to or embodying any minutes, agendas, brochures, memoranda or correspondence relating to meetings of any trade group or of any other group or association regarding the risk or occurrence of stroke,

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vasculitis, vasospasm or hypertension with the use of any PPA Product which were attended, supported or sponsored by Defendant.

64. Produce:

a. All documents relating or referring to medical seminars, conferences or lectures conducted, sponsored in whole or in part, or in which defendant or its agents participated, in which the topic of the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of a PPA Product was discussed;

b. All documents relating, referring to or embodying any presentations made by or on behalf of Defendant and any materials displayed, relied upon or distributed by Defendant at said conference.

G. PHYSICIANS AND SCIENTISTS

65. Produce every document relating, referring to or embodying any opinion by a physician, a scientist, or a medical or scientific expert, regarding the risk or occurrence of stroke, vasculitis, vasospasm or hypertensions with the use of PPA products, including but not limited to reports prepared in legal proceedings, opinions expressed in depositions or trial, reports submitted to scientific journals, opinions expressed at medical conferences, and opinions provided as testimony, reports or statements to the FDA or any foreign government regulatory authority, or any advisory committee thereof.

66. Produce all documents relating, referring to or embodying any financial payments, contributions or support provided by Defendant to any physician, scientist,

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medical or scientific expert which is the subject of the preceding request, or any institution, agency or entity with which said individual is affiliated.

67. Produce every document relating, referring to or embodying any attempt by Defendant to retain, engage or otherwise provide financial support or item of value to any person engaged in scientific or medical study of the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA Product.

H. DOCUMENTS CONCERNING LITIGATION

68. Produce all documents that you were requested to identify in response to Plaintiffs' Interrogatories.

69. Produce all documents from the files of the individuals identified in response to Plaintiffs' Interrogatories that relate or refer to the risk or occurrence of stroke, vasculitis, vasospasm or hypertension with the use of any PPA product.

70. Produce all documents upon which Defendant relies to support each and every affirmative defense asserted in the Answers filed to the Complaint of Plaintiffs.

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Respectfully Submitted,

Levinson Friedman, P.S.

Lance E. Palmer, Esq.
WSBA #18141
Plaintiffs' Liaison Counsel

Signed and submitted on behalf of,
and approval of, the individuals
listed below

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